EXHIBIT 7

Whitelaw Compliance Group, LLC.

Supplemental Report on the Examination of Compliance Standards for Opioid Manufacturers and Distributors

Prepared For	Prepared By
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION *IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION* Case No. 18-OP-45132 (N.D. Ohio) MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster	Dr. Seth B. Whitelaw President & CEO Whitelaw Compliance Group, LLC. May 10, 2019

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1 Introduction

As stated in my original report, I reserved the right to modify or supplement my conclusions as additional information became available to me, or as I performed further analyses. Since the submission of my report on April 15, 2019, three significant developments have occurred that warrant additional consideration. Those three developments are:

1. The settlement of the Rochester Drug Co-Operative case in the Southern District of New York.[1]
2. The testimony of the U.S. Drug Enforcement Administration's ("DEA") 30(b)(6) witness in this matter.[2]
3. The issuance by the U.S. Department of Justice ("DOJ") of updated guidance for evaluating corporate compliance programs.[3]

These developments expand on the discussion in Parts II and III of my original report. In addition to providing evidence that bears on the original report's conclusions, they also highlight the fact that good compliance is not a static endeavor but must adapt and evolve to remain effective.

Finally, as noted below, I also reviewed additional documents provided to me at my request that pertain to some of the specific companies examined in my report.

2 Rochester Drug Co-Operative

On April 22, 2019, the U.S. Department of Justice ("DOJ") and Rochester Drug Co-Operative ("RDC") entered into a five-year Deferred Prosecution Agreement ("DPA") to resolve charges that RDC from 2012 to March 2017 engaged in a conspiracy "to distribute controlled substances outside the scope of professional practice and not for a legitimate medical purpose," engaged in a conspiracy to defraud the United States, and "knowingly fail[ed] to furnish suspicious order reports to the U.S. Drug Enforcement Administration."[4] As described in the Statement of Facts included in the DPA, to which RDC agreed,[5] RDC "is a regional wholesale drug cooperative … that distributes … controlled substances to independently owned pharmacies in several states [and] … was

[1] *See* Deferred Prosecution Agreement between the U.S. Department of Justice and Rochester Drug Co-Operative, (Apr. 22, 2019) (including attached exhibits), ["RDC DPA"]; *see also U.S. v. Rochester Drug Co-Operative,* 19 C.r. (S.D. N.Y. 2019); *U.S. v. Laurence F. Dowd, III*, 19 CRIM. 285 (S.D.N.Y. 2019) (Mr. Dowd is RDC's CEO); *U.S. v. William Pietruszewski*, 19 Cr. __.(WHP) (S.D. N.Y. 2019) (Mr. Pietruszeski was RDC's former Chief Compliance Officer ("CCO")).

[2] *See* Thomas Prevoznik Deposition Parts 1 & II (Apr. 17-18, 2019).

[3] *See* U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs, 2 (updated Apr. 2019) (citations to the Justice Manual omitted), https://assets.documentcloud.org/documents/5983840/DOJ-Evaluation-of-Corporate-Compliance-Programs.pdf ["Evaluation Guidance 2019 Update"].

[4] *See* RDC DPA at 1.

[5] *Id.*

the fourth largest wholesale distributor in New York and one of the nation's ten largest distributors, with over 1,300 pharmacy customers and over $1 billion in revenue."[6]

A. General Framework Employed by the DOJ

During my examination of manufacturer and distributor compliance programs (both corporate and anti-diversion), I applied a framework utilizing the seven, now eight, elements of an effective compliance program found in the Federal Sentencing Guidelines, which were grouped as follows:

Category	Elements of an Effective Compliance Program
Company Commitment	1. Organization and Resources (including company culture)
Program Core	3. Written Standards 4. Training & Communication 5. Monitoring, Auditing & Investigations 6. Corrective Actions 8. Periodic Risk Assessments
Accountability	2. Due Diligence (i.e., avoiding bad actors) 7. Enforcement (i.e., Discipline or other consequences for violating the standards)

It appears that the DOJ applied a similar framework to assess RDC's anti-diversion efforts. It also appears that the DOJ observed conduct similar to that which I reviewed in my original report, and which underpins the DPA with RDC.

B. Evaluating Commitment to Compliance

In the course of its investigation, the DOJ examined both the staffing and resource levels devoted by RDC to its compliance department and anti-diversion program. The DOJ also examined the qualifications of the compliance department staff.

Based on that investigation, the DOJ noted that up until 2017 RDC "only had a handful of employees working in the compliance department, many of whom had little or no background in compliance," leading to the conclusion that RDC "failed to properly staff or provide sufficient resources to its compliance department."[7]

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[6] *See* RDC DPA at Exhibit C, 1, ¶3 ["Statement of Facts"].

[7] *See* Statement of Facts at 12, ¶ 23.

The DOJ also noted that RDC's senior management (CEO, COO and CCO) were aware of the DEA's requirements surrounding Know Your Customer and the other specific obligations under the CSA that applied to RDC (e.g., suspicious order monitoring).[8] The DOJ also found that RDC's senior management were warned that the company's approach to complying with its obligations for distributing controlled substances could be viewed as "willful blindness and deliberate ignorance"[9] by the DEA.

In evaluating RDC's cultural commitment to meeting its anti-diversion obligations, the DOJ found that statements by the CEO complaining about the financial burden of anti-diversion compliance efforts and his refusal to hire the necessary headcount requested by the CCO to be dispositive.[10] Likewise, the DOJ also connected the CEO's lack of compliance commitment to the fact that his bonus was tied to RDC's adjusted net earnings resulting in "a significant monetary incentive to bring on new customers that posed significant risks under the CSA [Controlled Substances Act]."[11]

C. Program Core

The DOJ, in the course of its investigation, carefully examined the core of RDC's program, and found several problematic issues.

First, when RDC received the Rannazzisi letters that were sent to all controlled substances registrants in 2006 and 2007,[12] the company had no anti-diversion program in place, and only after receiving the letters did it start formulating a program.[13] From 2011 onwards, RDC had policies and procedures governing its anti-diversion program, which included, among other things, maintaining a "red flags"[14] list of potential diversionary signals requiring further evaluation by RDC.

Even after RDC developed anti-diversion policies and procedures within the 2011 timeframe, it routinely failed to follow them. This lack of policy adherence included:

1. Failing to conduct due diligence on new accounts before distributing controlled substances.[15]
2. Failing to terminate problematic customers when evidence of "red flags" were uncovered, especially where the customers were "shareholders, board members or owed debts to RDC."[16]

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[8] *See id.* at 11, ¶ 21.

[9] *Id.*

[10] *Id* at 12, ¶ 24.

[11] *Id.* at 9, ¶ 18.

[12] Letters from J. Rannazzisi to All Registrants (Sep. 27, 2006, Feb. 7, 2007, Dec. 27, 2007).

[13] *See id.* at 20, ¶ 33.

[14] *See id.* at 9-10, ¶¶ 19-20.

[15] *See id.* at 25, ¶¶ 40-41.

[16] *See id.* at 18, ¶ 31 and 14-17, ¶¶ 28.b-28.e.

3. Failing to investigate or terminate customers purchasing large quantities of oxycodone or fentanyl.[17]
4. Failing to hold and not ship "orders of interest" without undertaking appropriate due diligence to determine why the orders "flagged" and that they were not indicators of diversion.[18]
5. Increasing customer thresholds to avoid them becoming "orders of interest"[19] which would require the blocking of shipments and further investigation by RDC.
6. Failing to report "orders of interest" to the DEA as suspicious orders, despite the fact that RDC's policies in place since at least 2009 "generally provided that an 'order of interest' was 'suspicious' if it deviated from legitimate business practices or evince a 'red flag' of diversion of controlled substances."'[20]

The DOJ highlighted that the impact of these failures resulted in RDC shipping over 1.5 million orders for controlled substances from 2012 to 2016, including approximately 8,300 "flagged" orders, while only reporting four suspicious orders to the DEA.[21]

D. Outcome

Under the DPA, RDC agreed to the facts set forth in the Statement of Facts and acknowledged responsibility for the acts of its officers and employees, as well as to pay $20 million as a stipulated forfeiture.[22] The company also agreed, consistent with importance of having a robust compliance program, to establish a standing Controlled Substances Compliance Committee, implement and maintain an effective compliance program, and accept oversight from an Independent Monitor to verify compliance with the DPA's provisions.[23]

E. Relevance

The RDC case, as noted previously, is relevant to my report for two reasons. First, the DOJ applied a similar framework to assess RDC's anti-diversion efforts that I independently applied in my assessment of the six companies I am offering opinions on in my report. Second, the failures noted for RDC by the DOJ also coincide with the failures I observed for each of the six companies including specifically: poor due diligence as to new customers, not holding or blocking "orders of interest" or "peculiar orders" until cleared by appropriate due diligence, inflating customer thresholds to avoid orders becoming "orders of interest" or "peculiar orders,"

[17] *See id.* at 14, ¶ 28.a. The DOJ noted in Statement of Facts that in the case of one customer, Pharmacy-1, in a single year its purchases of oxycodone increased from approximately 70,000 dosage units per month to over 200,000 per month.

[18] *Id.* at 29, ¶ 49.

[19] *See id.* at 30, ¶ 50.

[20] *See id.* at 26-27, ¶ 45.

[21] *See id.* at 27 ¶ 46 and 29, ¶ 49.

[22] *See id.* at 1-2.

[23] *See* RDC DPA at 6-8.

not investigating or terminating customers, as well as failing to report those customer orders to the DEA as "suspicious orders," when unresolved "red flags" were uncovered.

3 DEA's 30(b)(6) Testimony

Thomas Prevoznik, Acting Section Chief, Pharmaceuticals Investigations, Diversion Control Division, was designated by the DEA to provide the Agency's "interpretation and enforcement of and practices related to" the Controlled Substances Act ("CSA") and its accompanying regulations, as well as guidance provided by the DEA to controlled substances registrants.[24] Of specific importance to my original report, was his testimony surrounding the so-called shipping requirement and DEA's perspective on the appropriate use of Appendix E-3 in the Chemical Handler's Manual.[25]

A. The "Shipping Requirement"

The "shipping requirement" refers to the requirement embedded in the CSA's concept of an effective program to prevent diversion that registrants must hold or block suspicious orders and not ship them until those suspicions are dispelled. If those suspicions cannot be dispelled, the registrants must report the suspicious orders to the DEA and cancel the order.

At the outset, Mr. Prevoznik confirmed that DEA's expectation was that registrants "who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market are expressing an attitude of irresponsibility that is detrimental to the public health and safety …."[26] He confirmed that was the official policy of the DEA since at least 1996.[27]

The Chemical Handler's Manual also contains a provision stating that registrants should not ship suspicious orders until the suspicions are eliminated.[28] As Mr. Prevoznik testified, although this provision in the Manual pertains to List I chemicals, it is consistent "with the guidance DEA provided to registrants of controlled substances that do not include List I chemicals" (e.g., opioid products).[29] Once more, he confirmed that the

[24] *See* Thomas Prevoznik Deposition Part I, 20:14-18 (Apr. 17, 2019). Mr. Prevoznik is a 28-year veteran with the DEA. *Id.* at 26:13-14.

[25] *See* U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION CHEMICAL HANDLER'S MANUAL, 41 (Jan. 2004) at https://www.justice.gov/sites/default/files/open/legacy/2014/05/09/2004-chemical-handlers-manual.pdf. ["Chemical Handlers Manual, 2004 Edition"].

[26] *See* Thomas Prevoznik Deposition, Part II, 635:24-636:6 (Apr. 18, 2019).

[27] *Id.* at 636:17-19.

[28] *See* Chemical Handler's Manual, 2004 Edition, at 19 ("when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicious. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions.").

[29] *See* T. Prevoznik Deposition, Part II at 756:23-758:10.

DEA takes the position that "a registrant of controlled substances has a duty to block shipments of suspicious orders," and that this "[i]s now and always been the law of the United State of America."[30]

Thus, manufacturers and distributors have a duty to hold or block shipments of opioid orders that they determine to be suspicious.

B. Use of Appendix E-3

The issue with Appendix E-3 in the Chemical Handler's Manual refers to use of the "Factor of 3" by distributors as a basis for setting suspicious order thresholds for opioid products, which do not contain List I chemicals.[31] According to Mr. Prevoznik's testimony, if a distributor "is using E-3 to identify suspicious orders of unusual size, frequency or pattern" doing so was not "compliant with federal law, according to the DEA."[32] This is because "comparing a List I chemical to a controlled substance, is comparing apples to oranges."[33] Additionally, Mr. Prevoznik noted that he was not aware of the DEA ever endorsing a specific calculation to identify orders of unusual size, pattern, or frequency.[34] Therefore, this testimony confirms that use of Appendix E-3 to set suspicious order thresholds for opioid products was neither appropriate nor endorsed by the DEA.

4 DOJ Updated Guidance on Evaluating Corporate Compliance Programs

On April 30, 2019, the Justice Department released a guidance document on evaluating corporate compliance programs that updated "the prior version issued by the Division's Fraud Section in 2017."[35] According to the DOJ's press release, the updated guidance document "seeks to better harmonize the guidance with other Departments and standards while providing additional context to the multifactor analysis of a company's compliance program."[36] Assistant Attorney General Brian Benczkowski stated that "[e]ffective compliance programs play a critical role in preventing misconduct, facilitating investigations, and informing fair

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[30] *See id.* at 771:7-20.

[31] *See* U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION CHEMICAL HANDLER'S MANUAL, 41 (Jan. 2004) at https://www.justice.gov/sites/default/files/open/legacy/2014/05/09/2004-chemical-handlers-manual.pdf. ["Chemical Handlers Manual, 2004 Edition"].

[32] *See id.* at 759:19-760:7; *see also, id.* at 747:9-20 (discussing the fact that DEA has not provided guidance to registrants that use of the Factor of 3 was an appropriate threshold setting mechanism).

[33] *See id.* at 720:8-20.

[34] *See id.* at 735:2-6.

[35] Press Release from U.S. Department of Justice, Criminal Division Announces Publication of Guidance on Evaluating Corporate Compliance Programs (Apr. 30, 2019), https://www.complianceweek.com/regulatory-enforcement/justice-department-revises-the-evaluation-of-corporate-compliance-programs/26985.article

[36] *Id.*

resolutions," and therefore are part of the Department's "broader efforts … to help promote corporate behaviors that benefit the American public …."[37]

A. Fundamental Questions

At the outset, the updated guidance document suggests that there are three "'fundamental questions'" to ask about any corporate compliance program, which are:

1. "Is the corporations compliance program well designed?"
2. "Is the program being applied earnestly and in good faith?" In other words, is the program being implemented effectively?
3. "Does the corporation's compliance program work" in practice? [38]

The answers to these questions provide a rubric to determine whether the company's compliance program was effective. Importantly, it is also the same rubric embodied in the Federal Sentencing Guidelines and the framework of my original report.

B. Good Design

According to the guidance, the hallmark of a well-designed corporate compliance program is that it "is well-integrated into the company's operations and workforce."[39] Therefore, the guidance suggests that there are at least six areas to be explored: risk assessments, policies and procedures, training and communication, confidential reporting and investigations process, third party management, and mergers and acquisitions.[40] For the most part these areas mirror those found in the Federal Sentencing Guidelines and the framework of my original report.

In this section, the focus on critical attributes includes, but is not limited to, the risk assessment methodology employed,[41] the appropriate focus on high-risk areas,[42] the incorporation of the "cultural of compliance into … day-to-day operations," the understanding "by employees in practice … [to determine whether] the compliance program is 'truly effective,'" [43] the tracking, analyzing and utilization of information generated by the

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[37] *Id.*

[38] *See* U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs, 2 (updated Apr. 2019) (citations to the Justice Manual omitted), https://assets.documentcloud.org/documents/5983840/DOJ-Evaluation-of-Corporate-Compliance-Programs.pdf ["Evaluation Guidance 2019 Update"].

[39] *Id.* at 2.

[40] *See id.* at 2-8.

[41] *Id.* at 3.

[42] *Id.*

[43] *Id.* at 5

program,[44] including knowing "third-party partners' reputations and relationships,"[45] and the "real actions and consequences" for third-parties not passing "the company's due diligence."[46]

C. Effective Implementation

The updated guidelines stress that it is critical to probe a company's compliance program to determine whether it is a "'paper program' or one 'implemented, reviewed, and revised, as appropriate, in an effective manner.'"[47] Here the focus is on the commitment by both senior and middle management, the autonomy of and resources provided to the compliance program, and the incentive and disciplinary measures employed by the company.[48]

In case of the commitment to compliance, the guidance stresses it is not about just the "tone at the top." The updated guidance now stresses compliance commitment includes whether middle managers tolerate greater compliance risks "in pursuit of new business or greater revenues" and whether these same managers have "encouraged employees to act unethically to achieve business objectives or impeded compliance personnel from effectively implementing their duties."[49]

For the compliance department and its personnel, it is about seniority, experience, stature (e.g., stopping transactions that raise compliance concerns), as well as funding and resources.[50] In other words, regardless of the size of the company, "if a compliance program is to be truly effective, compliance personnel must be empowered within the company."[51]

Finally, in the case of incentive and disciplinary measures, it specifically is noted that it is not enough simply to discipline employees for malfeasance. Companies also need to consider "the implications of its incentives and rewards on compliance," including whether promotions or awards occur despite compliance and ethics considerations.[52]

D. Operation in Practice

According to the DOJ, "one hallmark of an effective compliance program is its capacity to improve and evolve" over time.[53] Therefore, it is important to see evidence of whether the company addressed both existing and

[44] *Id.* at 6.

[45] *Id.* at 7.

[46] *Id.* at 8.

[47] *Id.* at 9.

[48] *See id.* at 9-12.

[49] *Id.* at 9.

[50] *See id.* at 11.

[51] *Id.* at 10.

[52] *Id.* at 13.

[53] *Id.* at 14.

changing compliance risks and if misconduct occurs, "whether the company undertook an adequate and honest root cause analysis to understand both what contributed to the misconduct and the degree of remediation needed to prevent similar events in the future."[54] That root cause analysis needs to examine what controls failed as well as if there were "prior opportunities to detect the misconduct."[55]

5 Other Documents Pertaining to the Six Companies Reviewed

I also reviewed the following additional documents provided to me at my request.

A. McKesson Due Diligence Files

In the course of my review, I have reviewed additional due diligence files from Summit and Cuyahoga County pharmacies provided by McKesson that I did not cite to in my original report.[56] These are referenced here for the sake of completeness and transparency about the materials I have reviewed. These additional files do not change the conclusions reached in my report, but simply confirm those conclusions.

B. Additional Cardinal, CVS and Walgreens Documents

I also reviewed newly provided documents pertaining to Cardinal and Walgreens' anti-diversion programs.[57] For Cardinal, the documents pertain to an assessment of Cardinal's suspicious order monitoring program conducted by Cegedim in early 2008.[58] The CVS document is a descriptive overview of the Compliance Solutions Suspicious Order Monitoring System ("CCS-SOMS"), which details the system's algorithmic model.[59] [60]

The Walgreens' documents date to 2010 and 2011. The documents from 2010 involve the state of controlled substances dispensing training, including a discussion of what is contained within the Pharmacy Code of

[54] *Id.* at 13.

[55] *Id.* at 16-17.

[56] For a complete list of the additional documents reviewed, *see, infra* Appendix A.

[57] For a complete list of the additional documents reviewed, *see, infra* Appendix A.

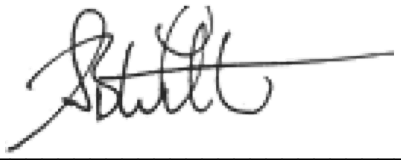
[58] *See* Letter and report from R. Buzzeo to J. Avergun (Jan. 23, 2008) (Ms. Avergun was Special Counsel with Cadwalader, Wickersham & Taft, LLP), CAH_MDL2804_03309960.

[59] *See* Cegedim Dendrite, *Descriptive Overview Document: Cegedim Dendrite Suspicious Order Monitoring (SOM) Model*, Version 1.0 (Dec. 2008), CVS-MDLT1-000123386

[60] I also have learned that CVS in the last week produced additional documents that may be responsive to the document requests I previously made of counsel. Again, for the sake of completeness and transparency, I note that I may receive and review these responsive documents along with other potentially responsive documents pertaining to the other companies reviewed in my report prior to my scheduled deposition.

Conduct.[61] The 2011 document discusses a Walgreens' initiative entitled "Florida Focus on Profit," which was implemented to address new Florida regulations governing pain management clinics.[62]

None of these additional documents, alter the conclusions reached in my report. Instead, they are confirmatory and supportive of those conclusions.



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[61] *See* Email and attachments from D. Pinon to C. Creek, *et al.*, Fw: DEA issue at 6094 (Jun. 28, 2010), WAGFLDEA00001861.

[62] *See* Email from R. Gates to E. Svihra, Florida Focus on Profit (Svihra) (May 20, 2011), WAGFLDEA0001890.

Appendix A

List of Additional Materials Considered

Except for the McKesson diligence documents, the lists below represent additional materials considered since the issuance of the original report dated April 15, 2019. All other materials cited to in this supplement were included in the original list of materials considered at Appendix I in the original report or in the case of the McKesson diligence materials were generally discussed, but not cited in their entirety.

A. Pertaining to Rochester Drug Cooperative

- Deferred Prosecution Agreement between the U.S. Department of Justice and Rochester Drug Co-Operative, (Apr. 22, 2019) (including attached exhibits).
- *U.S. v. Rochester Drug Co-Operative,* 1:19-cv-03568 (S.D. N.Y., Apr. 23, 2019).
- *U.S. v. Laurence F. Dowd, III*, 19 CRIM. 285 (S.D.N.Y. 2019).
- *U.S. v. William Pietruszewski*, 1:19-cr-00282 (S.D. N.Y. May 3, 2019).

B. Pertaining to the U.S. DEA's 30(b)(6) Testimony

- Deposition of Thomas Prevoznik, Parts I & II (Apr. 17-18, 2019).

C. Materials Pertaining to the U.S. DOJ's Guidance on Evaluating Corporate Compliance Programs

- Press Release from U.S. Department of Justice, Criminal Division Announces Publication of Guidance on Evaluating Corporate Compliance Programs (Apr. 30, 2019); https://www.justice.gov/opa/pr/criminal-division-announces-publication-guidance-evaluating-corporate-compliance-programs.
- U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs, (updated Apr. 2019), https://assets.documentcloud.org/documents/5983840/DOJ-Evaluation-of-Corporate-Compliance-Programs.pdf.

D. Other Documents Pertaining to the Six Companies Reviewed

- WAGFLDEA00001861
- WAGFLDEA00001890
- MCKMDL00496212-MCKMDL00496305
- MCKMDL00555448-MCKMDL00555744
- MCKMDL00568207-MCKMDL00568281
- CAH_MDL2804_03309958

- CAH_MDL2804_03309960
- CVS-MDLT1-000123386 – CVS-MDLT1-000123392